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09/596,370	06/19/2000	James M. White	1721-1	3966

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EXAMINER

CHORBAJI, MONZER R

ART UNIT	PAPER NUMBER
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1744

DATE MAILED: 12/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/596,370

Applicant(s)

WHITE, JAMES M.

Examiner

MONZER R CHORBAJI

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 September 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 June 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

This non-final action is in response to the RCE/Amendment received on 09/23/2004

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 21, 27 and 29 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In claim 21, line 7; applicant recites the feature "in valveless fluid communication". The specification and the drawings teach the use of valves (62 and 54) between the disinfectant line (unlabeled portion of the disinfectant line prior to valve 62) and the biological line (unlabeled portion of the biological line prior to valve 54). The specification on pages 6, 9, and 11 teaches of placing valves on the biological fluid line and the disinfectant line. Figure 1, shows valves 62 and 54 within the housing.

In claim 27, line 2; applicant recites the feature "a pipe in valveless communication with said biological fluid line within said housing". The disclosure indicates that valve 54 on the biological fluid line and is within the housing.

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In claim 29, line 4; applicant recites the feature "a disinfectant line having a valveless connection to said biological fluid line". The disclosure indicates indicated that valve 62 is on the biological fluid line within the housing.

The amendment received on 09/23/2004 with regard to claims 21, 27 and 29 does not present new matter. The issue of new matter is the concept of valveless, which is not supported by the disclosure.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

4. Claim 33 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 33, line10, applicant uses the term "coincides". The meaning of this term is not clear. Does the applicant mean by "coincides" that the flow of both the disinfectant line and the biological fluid line occupy the same place in space or time or such flows are in agreement with each other? Explanation is needed to understand the meaning of such a term.

Claim Objections

5. Claim 27 is objected to because of the following informalities:

In claim 27, line 2; applicant uses the word "communicating". Such a word should be replaced with "communication". Appropriate correction is required.

Claim Rejections - 35 USC § 103

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6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 21-25, 29-31, and 33-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jackson (U.S.P.N. 5,087,420) in view of Aubrey et al (U.S.P.N. 3,857,409) and further in view of Kern, Jr. et al (U.S.P.N. 6,000,418).

With respect to claims 21, 29, and 33, the Jackson reference discloses a method and a device for disposal of biological fluids (col.1, lines 57-60) such that the device includes a housing (11), a water flow inlet (20) and an outlet (22), a biological fluid line (col.3, lines 33-36) such that the water fluid line and the biological fluid line are mixed together (20, 24, and 26). The Jackson reference further teaches a disinfectant line (32) in communication with the water flow line (water inside 26) such that the disinfectant line has an inlet outwardly of the housing (23). Further the disinfectant line (32 and water within 26) and the biological fluid line (24 and water within 26)) are connected with the water flow line. The Jackson reference further includes a disinfectant line (32)

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connected in valveless fluid communication (no valves are present on both the biological fluid line and the disinfectant line) with biological fluid line (24) between the water flow line (30) and an inlet of the biological fluid line (38 and 36) wherein the biological fluid line being substantially blood (col.1, lines 59-60). The disinfectant line and the biological fluid line are in communication within the housing (36 and 11). Furthermore, the disinfectant line (32) is in fluid communication with the water flow line (water inside 26). The Jackson reference goes on to disclose a method of disposing biological fluids (col.4, lines 51-68 and columns 5-6) including the following steps: connecting the biological fluid line in valveless relation to a disinfectant line (24 is connected to 32 through 26) at a connection point (32), connecting a water flow line to an outlet of the biological fluid line and the disinfectant line (30 is connected to the outlets of 38 and 32), mixing the biological fluid and the disinfectant together (mixed in 26), and discharging the water and the mixed biological fluid and disinfectant from water flow line (22). The biological fluid flow in fluid line and the disinfectant flow in the disinfectant line coincide (both 24 and 32 mix together in 26 and both occupy the same place in time) together. However, the Jackson reference fails to teach that solely the flow of water causes the suction and mixing of both the disinfectant and the biological fluid lines (venturi means) and the housing contains no pumps. The Aubrey reference housing includes no pumps (col. 7, lines 64-67 and col.8, lines 1-6), but there is no teaching that solely the flow of water causes the suction and mixing of both the disinfectant and the biological fluid lines. The Kern reference discloses the concept that the flow of water causes the suction and mixing of different fluids (col.5, lines 17-23).

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For example, the flow of the diluent in channel (33) determines the suction action of the injectate in channel (39). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to delete the pump (37) of the Jackson reference and substitute the venturi effect of mixing of the Kern reference for the known and expected result of being able to mix fluids in the absence of any pumps to provide movement of the fluids to be mixed.

With respect to claim 22, the Jackson reference discloses a device having water flow inlet (20) means and outlet means (22) such that the inlet means is for passing water and the outlet means for releasing a mixture of the biological fluid and the water and the disinfectant (col.6, lines 41-45).

With respect to claim 23, the Jackson reference discloses a device that includes a water inlet (20) communicating with one end of water flow line (30a) and an outlet means (22) connected to water flow line (46) on an opposite end of water flow line such that outlet means for passing a flow of liquid to a sewer (col.6, lines 46-47).

With respect to claim 24, the Jackson reference device includes a pipe (39) communicating with the water flow line (30) such that both communicate with each other through 26), the disinfectant line (32) having a connection to the pipe (connection between 32 and 26) at a distance from the water flow line (30) and between an inlet of the pipe (unlabeled inlet for 39) and water flow line (30) such that the biological fluid (38) mixing with the disinfectant (32) in pipe (39).

With respect to claim 25, the device of the Jackson reference places a valve (40) along the pipe (39) along the such that if for example the valve (40) is opened then the

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rate of the biological fluid is reduced since all the biological fluid is emptied from (26) to reservoir (27). However, the Jackson reference fails to place a valve between the inlet of the pipe and the connection to the disinfectant line. The device in the Kern reference includes a valve (unlabeled in figure 2 within the area A) connected to the pipe (unlabeled part of 26 between the valve and 22 within the area A) between the inlet of the pipe (unlabeled connection between the valve and the pipe in figure 2 within the area A) and connection to the injection tube 21. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to place the valve between inlet of the pipe and connection to the disinfectant in the Jackson apparatus since such a modification is a matter of choice of design of the artisan evidenced by the Kern reference.

With respect to claim 31, the Jackson reference teaches that the treated fluid is interconnected to a sewer (22 and col.6, lines 45-47).

With respect to claim 34, the Jackson reference discloses a method that includes connecting the disinfectant line (32) to the biological fluid line (38 through 26) between an inlet of the biological fluid line (36) and the outlet of the disinfectant line (outlet of 32).

With respect to claim 30, the Kern reference discloses the concept of venturi means such that solely a water flow across openings of various different fluids creates a suction force (col.5, lines 17-23).

9. Claims 26-28, 32, and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jackson (U.S.P.N. 5,087,420) in view of Aubrey et al (U.S.P.N.

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3,857,409) and further in view of Kern, Jr. et al (U.S.P.N. 6,000,418) and Griffiths (U.S.P.N. 5,914,047).

With respect to claims 26-28, 32 and 35, the Jackson, the Aubrey and the Kern references all fail to disclose containers for biological and disinfectant fluids such that the fluid lines are inserted into the containers, however; the Griffiths reference discloses the following: a suction line for insertion into a biological fluid container (70A), a biological fluid container (46A) having a top level (68), inserting an inlet of the biological fluid line into a container of biological fluid (col.7, lines 33-35), a disinfectant container (80) having a top level (82), and a suction line for insertion into a disinfectant fluid container (84). Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method and the device of the Jackson reference to include a biological fluid container as taught by the Griffiths reference since it functions as a container for untreated liquid waste (col.7, lines 31-32).

Response to Arguments

10. Applicant's arguments filed on 09/23/2004 have been fully considered but they are not persuasive.

On page 7 of the Remarks section, applicant argues that, "Both figure 1 and figure 2, in addition to page 10 of the specification adequately disclose the valveless junction at the physical connection between the biological fluid line and the disinfectant line." Claims 21, 27 and 29 are rejected under new matter because figure 1 shows valves 62 and 52 on the disinfectant line and the biological fluid line such that the valves are within the housing 12. Amended claim 33 was not rejected under new matter since it

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recites the limitation "valveless at a connection point". Such a limitation was not recited in claims 21, 27 and 29.

On pages 10-11 of the Remarks section, applicant has individually questioned each reference instead of rebutting the motivation for combining the references. The Aubrey reference and the Kern reference are in the art of mixing fluids just like the instant claims are.

On page 11 of the Remarks section, applicant argues that, "The Aubrey patent does not teach a pumpless and valveless structure within the housing." The examiner disagrees. The Aubrey reference housing includes no pumps (col. 7, lines 64-67 and col. 8, lines 1-6) and further, figure 1 of the instant application does teach valves (62 and 54) within the housing (12).

On page 11 of the Remarks section, applicant argues that, "The concept of venturi and suction by water flow is disclosed; however, the inter-relationship between two fluids with related venturi effects, as now clarified in the amended claim 21, are not disclosed by the Kern patent." The examiner disagrees. The Kern reference teaches (col. 5, lines 29-32) that the additive lines are connected to supply sources such that it is intrinsic to the Kern's apparatus that if one additive source is empty then the flow of the other additives will be affected as. Thus, establishing an inter-relationship based on more than one venturi effect between the additive lines.

On page 12 of the Remarks section, applicant argues that, "The valve means outside of the housing is taught against in the Aubrey patent, and the connection point of the two fluids is not disclosed by the multiple inlet ports in parallel relation of the Kern

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patent.” The examiner disagrees. The Aubrey reference is combined for having a pumpless system and not for the limitation of the valves being outside the housing. The Kern reference is combined for teaching the concept of the venturi effect and not for feature having a connection point of the two fluids. Such features have been addressed in the Jackson reference as shown above.

On page 12 of the Remarks section, applicant argues that, “Claims 29 and 33 have been amended to clarify the valveless relation at the connection point within the housing, which is not disclosed by either the Jackson patent or the Aubrey patent.” As shown above, with respect to amended claims 29 and 33, the Jackson reference does teach such limitations. The Aubrey reference is only combined to show that a housing is known not to include any pumps.

On page 12 of the Remarks section, applicant argues that, “Additionally, the coinciding flow of disinfectant and flow of biological fluid is not taught by the Kern patent.” As explained above, the feature of coincidence between the flow of the disinfectant and biological fluids has been addressed with respect to the Jackson reference. Again, the Kern reference is only combined to show that the concept of applying the venturi effect is known in the art of mixing fluids.

On page 13 of the Remarks section, applicant argues that, “Fundamentally, it is very difficult to see how the unrelated fields of art can be combined, in any way.” The examiner disagrees. All the references used are in the art of mixing fluids. The Aubrey reference and the Kern reference are in the art of mixing fluids.

Conclusion

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11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MONZER R CHORBAJI whose telephone number is (571) 272-1271. The examiner can normally be reached on M-F 6:30-3:00.

12. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ROBERT J WARDEN can be reached on (571) 272-1281. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

13. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Monzer R. Chorbaji *MRC*
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